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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,186	03/03/2004	Mark Shu	MI90,148,101 / P-11480.00	4896
25281 7590 10/15/2008 DICKE, BILLIG & CZAJA FIFTH STREET TOWERS 100 SOUTH FIFTH STREET, SUITE 2250 MINNEAPOLIS, MN 55402				
EXAMINER				
STEWART, ALVIN J				
ART UNIT		PAPER NUMBER		
3774				
MAIL DATE		DELIVERY MODE		
10/15/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/792,186

Applicant(s)

SHU ET AL.

Examiner

Alvin J. Stewart

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008 & 07/11/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 54-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31, 54, 55, 57 and 58 is/are rejected.
- 7) ☒ Claim(s) 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed 09/04/07 have been fully considered but they are not persuasive.

After a careful examination of the new limitations and the Applicant's remarks the Examiner believes that the previous rejection is still proper. The new limitations that describe how the suture segment is circumferentially pulled relative to at least one of the flanges do not add structure limitations that would overcome the prior art.

In order to overcome the rejection the Applicant's representative has to positively claim the suture segment. For the moment, the Examiner does not need to find a suture segment because is not positively claimed.

The examiner suggest the following in order to overcome the rejection: in line 6 after the phrase : "the second flange" the following should be entered --a suture segment circumferentially pulled relative to at least one of the flanges...---. Instead of using the wherein clause.

The Examiner wants to clarify to the Applicant's representative that the limitations in claim 1, lines 7-10 are only functional language. The Examiner has given weight to the wherein clause, but the Examiner has to only look for a suture locking assembly that is capable of being pulled relative to at least one flange. A "wherein" clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim. See *Texas Instruments Inc. v. International Trade Commision*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 Uspq2d 1747 (Fed. Cir. 2001).

This phrase has been identified as an intended use limitation because is typical of claim limitations which may not distinguish over prior art according to the principle. It has been held that the recitation that an element is “configured to” performing a function is not a positive limitation but only requires the ability to so perform.

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 13-31 and 54, 55, 57 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Purdy et al US Patent 5,562,729.

Purdy et al discloses a suture locking assembly (see Figures 34-37) comprising a rim (202) defining a first flange (204) and a second flange (204) (see col. 10, lines 25-28), the rim is configured to extend at least partially around a periphery of the heart valve. A suture band, (see undisclosed circular ring between elements 204 in Fig. 35) wherein the suture locking assembly is configured to securely maintain a suture segment that is pulled from a first position to a second position relative the suture locking assembly.

Again the examiner wants to point out that the wherein clause of claim 1, “wherein the suture locking assembly...” is disclosing functional language and the Examiner is looking for a

device capable of disclosing the functional language. Regarding the positions, the first position is the position of element 176 before connecting to the flanges 204 of the heart valve. The second position is the lock position shown in Figure 35.

NOTE: the examiner wants to point out that the Applicant's representative is not positively claiming a suture segment and again the Examiner is looking for a device capable of securing a suture segment between the rim and the suture band.

Regarding claims 2 and 3, again the examiner is looking for a device capable of performing the claimed function.

Additionally, Purdy et al discloses a different embodiment and can be interpreted as follow: rim (19) (see Figs. 4-4B) defining a first flange (upper section of element 19, see element 26 in Fig. 4A) and a second flange (see lower section of element 19, see element 38 in Fig. 4A) and a suture band (28) and the suture band has a suture segment (see Fig. 7 element 38).

Regarding claim 5, the examiner has interpreted the distal ends of each flange as the plurality of stop sites. The ends of the flanges are capable of impeding suture movement.

Regarding claims 8 and 9, the examiner has not given patentable weight to the functional language "configured to".

Regarding claims 11 and 13, see fig. 34.

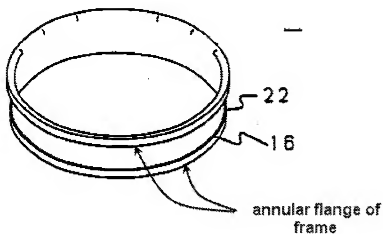
Claims 1-31 and 54, 55, 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauter et al US Patent 5,071,431.

Sauter et al discloses a heart valve (see Fig. 1) comprising an annular valve body (see Fig. 2) comprising a rim (16), at least one outwardly extending annular flange extending from the rim (see Figure A below), a band (24) having at least one inwardly extending

Art Unit: 3774

annular flange (see flanges in band 24 Figures 2 & 4), wherein a portion of the flange is capable of engagement with a portion of the annular flange of the frame. Finally, at least one locking tab (32 or 112) that includes at least one barbed portion (114 & 116 the Examiner interpreted the free end portion of elements 114 and 116 as the barbed portion because the elements 114 and 116 have a sharp portion).

Figure A



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy et al US Patent 5,562,729.

Purdy et al discloses the invention substantially as claimed. However, Purdy et al does not disclose a homogenous rim formed with a stent.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the manufacturing process of the heart valve by making the device of the same material because Applicant has not disclosed that by having a homogeneous material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Purdy et al reference because no matter how the implant is made it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the Purdy et al reference to obtain the invention as specified in claim 1.

Allowable Subject Matter

Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

October 07, 2008.

Application Number**Application/Control No.**

10/792,186

Examiner

Alvin J. Stewart

**Applicant(s)/Patent under
Reexamination**

SHU ET AL.

Art Unit

3774